

12-Person Jury

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IRIS Y. MARTINEZ
CIRCUIT CLERK
COOK COUNTY, IL
13277136

KATHLEEN BIESTERFELD, Individually)
as Mother & Next Best Friend of)
NICHOLAS BIESTERFELD, and)
RONALD BIESTERFELD,)
Plaintiffs,)
v.)
ARIOSA DIAGNOSTICS, INC.; ARIOSA)
DIAGNOSTICS CLINICAL)
LABORATORY; and HARMONY)
PRENATAL TESTING,)
Defendants.)

2021L004834
No.

COMPLAINT AT LAW

COUNT I—VIOLATION OF CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

1. At all times Plaintiffs resided in the City of Roselle, County of DuPage, State of Illinois.
2. Plaintiffs' son, NICHOLAS BIESTERFELD, receives treatment from medical providers and therapists operating out of Cook County, Illinois.
3. Defendant ARIOSA DIAGNOSTICS, INC. is a corporation headquartered in the City of San Jose, County of Santa Clara, State of California.

4. ARIOSA DIAGNOSTICS CLINICAL LABORATORY is a division of ARISOA DIAGNOSTICS, INC. and is also located in the City of San Jose, County of Santa Clara, State of California.

5. Defendants engage in continuous and substantial business in Illinois including all counties.

6. Plaintiffs utilized Harmony Prenatal Test when Plaintiff KATHLEEN BIESTERFELD was pregnant with Plaintiffs' son, NICHOLAS BIESTERFELD.

7. Defendants represented that the Harmony Prenatal Test would safely and easily test the fetal DNA of NICHOLAS BIESTERFELD for Down syndrome and other genetic abnormalities.

8. Harmony Prenatal Test only tests placental DNA, not fetal DNA.

9. Harmony Prenatal Test was aggressively and falsely sold, promoted, distributed and/or marketed by defendants as a reasonable alternative to amniocentesis and as a reliable means to detect chromosomal abnormalities including Trisomy 21. (Attached hereto as Exhibit "A" is the online advertising from Defendants' website from May 2018).

10. On July 23, 2017, the Defendants generated a report indicating that the chances that NICHOLAS BIESTERFELD would have a chromosomal anomaly for fetal Trisomy 21 was less than 0.1%.

11. Defendants did not disclose to KATHLEEN BIESTERFELD and RONALD BIESTERFELD the Harmony Prenatal Test produced T21 false negatives by only testing placental DNA.

12. NICHOLAS BIESTERFELD was born on February 6, 2018, and presented with clear signs of Down Syndrome.

13. Plaintiffs bring this cause of action pursuant to 815 ILCS 505/2, the Consumer Fraud and Deceptive Business Practices Act, in their individual capacities.

14. Section 2 of the Consumer Fraud and Deceptive Business Practices Act provides that it is unlawful to use “unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact.”

15. Defendants used unfair or deceptive acts or practices in one or more of the following ways:

- A. Misrepresenting that Harmony Prenatal Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
- B. Misrepresenting that Harmony Prenatal Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
- C. Misrepresenting the limitations of and alternatives to Harmony Prenatal Test;
- D. Misrepresenting that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
- E. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;
- F. Misrepresenting the probability and rate at which the Harmony Prenatal Test could produce false negative results; and
- G. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of Harmony Prenatal Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.

16. Defendants made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.

17. Defendants knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.

18. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.

19. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.

20. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.

21. As a direct and proximate result of the misrepresentations made and unfair and deceptive acts and business practices conducted by Defendants, Plaintiffs sustained injuries, harm, and economic loss for the past, present, and future.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, plus punitive damages, together with the costs of this action.

COUNT II—COMMON LAW FRAUD

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

22. Plaintiffs restate and re-allege paragraphs 1-12 of Count I as their paragraphs 22 through 33 of Count II.

34. Defendants made false statements of material fact in one or more of the following ways:

- A. Misrepresenting that Harmony Prenatal Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
- B. Misrepresenting that Harmony Prenatal Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
- C. Misrepresenting the limitations of and alternatives to Harmony Prenatal Test;
- D. Misrepresenting that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
- E. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested; and
- F. Misrepresenting the probability and rate at which Harmony Prenatal Test could produce false negative results.

35. The aforesaid representations and/or statements made by Defendants regarding Harmony Prenatal Test were false.

36. Defendants knew or had reason to know that the aforesaid representations and/or statements were false when the Defendants made such statements and/or representations.

37. Plaintiffs reasonably believed Defendants' aforesaid representations and/or statements regarding Harmony Prenatal Test were true.

38. Defendants made the aforesaid false representations and/or statements as a means to induce Plaintiffs and others similarly situated to Plaintiffs to choose, buy, use, and order Harmony Prenatal Test.

39. Plaintiffs reasonably relied on the aforesaid representations and/or statements made by Defendants when Plaintiffs chose Harmony Prenatal Test as their method of prenatal testing during Plaintiff KATHLEEN BIESTERFELD'S pregnancy.

40. As a result of Defendants' aforesaid false representations and/or statements, Plaintiff KATHLEEN BIESTERFELD did not undergo any other testing to detect Trisomy 21 abnormalities.

41. Harmony Prenatal Test failed to detect an abnormality of Trisomy 21 during the pregnancy of Plaintiff KATHLEEN BIESTERFELD.

42. Plaintiffs' results from Harmony Prenatal Test indicated that Plaintiffs' son did not have a Trisomy 21 abnormality.

43. As a direct and proximate result of the foregoing, Plaintiffs' son, NICHOLAS BIESTERFELD, was born with Down Syndrome.

44. As a direct and proximate result of the foregoing, Plaintiffs have suffered injuries, harm, and economic loss, including past, present, and future.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, plus punitive damages, together with the costs of this action.

COUNT III—BREACH OF EXPRESS WARRANTY

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys,

VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

45. Plaintiffs restate and re-allege paragraphs 1-12 of Count I as their paragraphs 45 through 56 of Count III.

57. Defendants marketed, sold, and distributed Harmony Prenatal Test, promoted the product, and expressly warranted to Plaintiffs that Harmony Prenatal Test was fit for the ordinary purpose for which it was intended, specifically that it is a reliable and accurate form of prenatal testing.

58. Specifically, Defendants advertised, promised, and warranted that Harmony Prenatal Test had a 100% accuracy rate in detecting abnormalities of Trisomy 21.

59. Plaintiff KATHLEEN BIESTERFELD chose to utilize Harmony Prenatal Test because she wanted to test NICHOLAS BIESTERFELD's DNA during her pregnancy to determine whether NICHOLAS BIESTERFELD had a Trisomy 21 abnormality with 100% certainty.

60. Harmony Prenatal Test failed to detect that NICHOLAS BIESTERFELD had a Trisomy 21 abnormality and would be born with Down's syndrome.

61. Harmony Prenatal Test did not have a 100% accuracy rate in detecting abnormalities of Trisomy 21 as warranted by Defendants because Harmony Prenatal Test failed to detect that NICHOLAS BIESTERFELD had a Trisomy 21 abnormality.

62. Defendants' representations and warranties were false, misleading, and inaccurate in that Harmony Prenatal Test is risky and unreliable and can and does lead to false negatives in testing for Down Syndrome.

63. As a foreseeable, direct, and proximate result of the aforesaid conduct of the Defendants, Plaintiffs suffered severe and permanent injuries to their person.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, together with the costs of this action.

COUNT IV—BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

64. Plaintiffs restate and re-allege paragraphs 1-12 of Count I as their paragraphs 64 through 75 of Count IV.

76. At all relevant times, Defendants manufactured, distributed, recommended, merchandized, advertised, promoted, and sold Harmony Prenatal Test as a reliable, effective, and safe way of detecting Trisomy 21 abnormalities in fetuses.

77. Defendants placed Harmony Prenatal Test into the stream of commerce.

78. Plaintiff KATHLEEN BIESTERFELD utilized Harmony Prenatal Test to determine if NICHOLAS BIESTERFELD had a Trisomy 21 abnormality.

79. Defendants marketed, distributed, and advertised Harmony Prenatal Test as having a 100% accuracy rate in detecting abnormalities of Trisomy 21.

80. 810 ILCS 5/2-314(2)(f) sets forth that a good is not merchantable if it does not conform to the promises or affirmations of fact made on the container or label if any.

81. Harmony Prenatal Test did not have a 100% accuracy rate in detecting Trisomy 21 abnormalities because it did not detect that NICHOLAS BIESTERFELD had a Trisomy 21 abnormality.

82. Plaintiffs discovered that Harmony Prenatal Test did not have a 100% accuracy rate in detecting Trisomy 21 abnormalities upon the birth of NICHOLAS BIESTERFELD.

83. The Plaintiffs alerted Defendants of this breach of merchantability on March 4, 2019 via correspondence from Plaintiff's counsel to Defendants.

84. Harmony Prenatal Test was not of merchantable quality, as warranted by Defendants, in that it is unreliable, unsafe, and of limited utility for detecting Down Syndrome in patients like Plaintiff KATHLEEN BIESTERFELD and was thus not fit for the ordinary purpose for which it was intended.

85. As a foreseeable, direct, and proximate result of the aforesaid conduct of the Defendants, Plaintiffs suffered severe and permanent injuries to their person.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, together with the costs of this action.

COUNT V—NEGLIGENCE

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSA DIAGNOSTICS, INC.; ARIOSA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

86. Plaintiffs restate and re-allege paragraphs 1-12 of Count I as their paragraphs 86 through 97 of Count V.

98. Defendants had a duty to Plaintiffs to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, selling, and/or distributing Harmony Prenatal Test into the stream of commerce.

99. Notwithstanding the aforesaid duty, Defendants deviated from the exercise of reasonable and ordinary care in one or more of the following careless and negligent acts and/or omissions:

- a. Failed to inform Plaintiffs and others similarly situated that Harmony Prenatal Test was not fit, effective, and/or adequate for human use in detecting Down Syndrome;
- b. Misrepresented to Plaintiffs and others similarly situated that Harmony Prenatal Test did not have a 100% accuracy rate in detecting abnormalities of Trisomy 21;
- c. Misrepresented to Plaintiffs and others similarly situated the limitations of and alternatives to Harmony Prenatal Test;
- d. Misrepresented to Plaintiffs and others similarly situated that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
- e. Misrepresented to Plaintiffs and others similarly situated that fetal DNA was being tested when, in actuality, only placental DNA was being tested; and
- f. Omitted from Plaintiffs and others similarly situated the probability and rate at which Harmony Prenatal Test could produce false negative results.

100. As a direct and proximate result of one or more of the aforesaid acts or omissions by Defendants, Plaintiffs suffered injuries, harm, and economic loss and Plaintiffs will continue to suffer such injuries, harm, and economic loss.

101. As a foreseeable, direct, and proximate result of Defendants' conduct, Plaintiffs have suffered, and will continue to suffer, emotional distress and financial costs in raising a child with Down Syndrome.

102. As a foreseeable, direct, and proximate result of Defendants' conduct, Plaintiffs have and will continue to suffer loss of income and earnings, past, present, and future and earning capacity.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000 together with the costs of this action.

Respectfully submitted,



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